REMARKS

This Response is submitted in reply to the final Office Action mailed on October 4, 2011. No fees are due herewith this Response. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02–1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036–00755 on the account statement.

Claims 1–11 and 13–14 are pending in the application. Claims 8–11 and 13–14 were previously withdrawn. Claim 12 was previously canceled without disclaimer. In the Office Action, Claim 1 is rejected under 35 U.S.C. §112, Claims 1 and 4–7 are rejected under 35 U.S.C. §102, and Claims 1–7 are rejected under 35 U.S.C. §103. In response, Claim 1 has been amended, and Claim 4 has been canceled without disclaimer. The amendments do not add new matter. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully request that the rejections be withdrawn.

In the Office Action, Claim 1 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Patent Office states that the specification does not provide support for a liquid product having a pH of about 4 to about 7.5. See, Office Action, page 3, lines 8–15. Applicants respectfully disagree and submit that the specification does provide support for a liquid product with a pH of about 4 to about 7.5 on page 11, lines 6–9. For example, the specification states "[t]he product may have any pH in the range of 3.4–8, preferably 4–7.5..." As a result, the skilled artisan would understand that this pH range is supported by the originally filed specification.

Based on at least these noted reasons, Applicant believes that Claim 1 fully complies with 35 U.S.C. §112, first paragraph. Accordingly, Applicant respectfully requests that the rejection of Claim 1 under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claims 1 and 5–7 are rejected under 35 U.S.C. §102(b) as being anticipated by "Storage Stability of Vegetables Fermented with pH Control," Journal of Food Science 1983, Vol. 48, p. 975-981 to Fleming et al. ("*Fleming*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Currently amended independent Claim 1 recites, in part, a water- or milk-based liquid product comprising living microorganisms selected from the group consisting of

Bifidobacterium, *Streptococcus*, *Lactococcus*, *Enterococcus* and mixtures of the same. The amendments do not add new matter and are supported by the specification at, for example, page 8, lines 23–25. The liquid product has a pH from about 4 to about 7.5 and shelf-life of at least 1 month at 10°C. The liquid product is free of carbohydrates that can be metabolized by the microorganisms.

As is described in detail in the specification, the presently claimed products are shelf-stable because the microorganisms contained therein are able to survive for several months at room temperatures due to their inability to metabolize nutrients contained in the product. See, specification, Abstract. Indeed, the fact that many probiotic bacteria possess an anaerobic metabolism imposes specific technical requirements on all process and product levels between a starting culture and a consumable product suitable to deliver the bacterium in a sufficiently high concentration to a human or animal. See, specification, lines 31–34. Further, the mere fact that living bacteria are metabolically active—even at chilled temperatures—imposes problems: for example, ingestible carriers of probiotics often sustain degradation by the bacterial activity, which may render the carrier completely unpalatable. See, specification, page 1, line 36–page 2, line 2.

One way of delivering a probiotic is the preparation of a material, which was fermented by the probiotic. This is the case, for example, with yogurts that were obtained from fermenting milk with micro-organisms. An advantage of these products is that they are relatively stable when chilled, due to the low pH of the product after fermentation. However, the acid produced by the fermenting activity of the probiotic does not correspond to every consumer's taste. In addition, these products still have to be chilled. See, specification, page 2, lines 21-27. Thus, prior art products having microorganisms may suffer from a number of deficiencies including, for example, the inability to provide a sufficient concentration of the microorganism to the subject, or unpalatability.

In contrast, however, Applicants have surprisingly found that providing microorganisms selected from the group consisting of *Bifidobacterium*, *Streptococcus*, *Lactococcus*, *Enterococcus* and mixtures of the same in a product that does not contain carbohydrates that may be digested by the microorganism results in a product that is shelf-stable for extended periods of time and provides a sufficient amount of microorganisms to the subject. As is further described

in the specification, the products according to the present disclosure may be fermented products, which are obtained, for example, by fermenting a medium, heat treating or pasteurizing the medium to reduce bacterial load, and, at the same time, kill the fermenting bacteria. Then the fermented products could be supplemented with a micro-organism, which will not further grow on the fermented medium. For example, the products may be a yogurt, which is heat-treated and to which micro-organisms that are not able to grow on the fermented, heat-treated product are added, in order to obtain products that fulfill the features of the present claims. See, specification, page 6, lines 20-32.

In contrast, Applicants respectfully submit that *Fleming* fails to disclose or suggest each and every element of the present claims. Specifically, *Fleming* fails to disclose or suggest a water- or milk-based liquid product comprising living microorganisms selected from the group consisting of *Bifidobacterium*, *Streptococcus*, *Lactococcus*, *Enterococcus* and mixtures of the same and has a pH from about 4 to about 7.5 as required by independent Claim 1.

Fleming is entirely directed to storage of a vegetable product in sealed jars at about 24°C having all fermentable sugars removed from the vegetables during fermentation and stored at a pH of 3.8 or below. See, *Fleming*, Abstract. The Patent Office alleges that *Fleming* discloses that the product is kept at a pH of above 4. See, Office Action, page 4, lines 7–8. Applicants respectfully disagree and submit that the preservation process in *Fleming* begins with a product at a pH of 4.5, but that the final product is kept at a pH of 3.8 or below. See, *Fleming*, page 976, 3rd paragraph, line 3. Consequently, *Fleming* does not disclose a final product that is a liquid having a pH of about 4 to about 7.5 in accordance with independent Claim 1.

Also, *Fleming* does not disclose the addition of living microorganisms selected from the group consisting of *Bifidobacterium*, *Streptococcus*, *Lactococcus*, *Enterococcus* and mixtures of the same to the liquid product. Although *Fleming* discloses a culture of *Lactobacillus plantarum*, *Fleming* fails to disclose or suggest that any other species or genera of probiotic could be used in the product.

For at least the reasons discussed above, *Fleming* fails to disclose or suggest each and every element of independent Claim 1. As a result, Applicants respectfully submit that independent Claim 1, along with any claims that depend from Claim 1, is novel, nonobvious and distinguishable from *Fleming*.

Accordingly, Applicant respectfully requests that the anticipation rejection with respect to Claims 1 and 5–7 be reconsidered and the rejection be withdrawn.

In the Office Action, Claims 1–7 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Fleming* and WO 00/53202 to Reniero et al. ("*Reniero*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

As discussed above, amended independent Claim 1 recites, in part, a water- or milk-based liquid product comprising living microorganisms selected from the group consisting of *Bifidobacterium*, *Streptococcus*, *Lactococcus*, *Enterococcus* and mixtures of the same. The liquid product has a pH from about 4 to about 7.5 and a shelf-life of at least 1 month at 10°C and is free of carbohydrates that can be metabolized by the microorganisms.

As previously discussed, *Fleming* is deficient with respect to the present claims. *Reniero* fails to remedy the deficiencies of *Fleming*. The Patent Office recognizes that *Reniero* does not teach a liquid product that is free of carbohydrates that can be metabolized by the *Lactobacillus*. See, Office Action, page 5, lines 17–27. Instead, *Reniero* is entirely directed to the prevention of diarrhea brought about by rotaviruses and pathogenic bacteria using microorganisms from the genus *Lactobacillus*. See, *Reniero,* Abstract. Indeed, *Reniero* expressly discloses that the microorganisms (e.g., lactic acid bacterium) used in the compositions must be capable of growing in the presence of bile salts in a composition of up to about 0.4% and may essentially prevent invention of epithelial cells by rotaviruses. See, *Reniero,* page 3, lines 27-31. *Reniero* refers to liquid products comprising a strain such as *Lactobacillus paracasei* CNCM I-2116, which may be grown, for example, in tomato powder rehydrated with distilled water and used as inoculum.

Tomatoes contain different kinds of carbohydrates. Storage is performed at 10°C for up to 30 days employing a medium comprising 2% wheat flour, 3% rice flour and 3% sucrose, i.e., a medium containing different kinds of carbohydrates in high amounts. *Reniero* clearly discloses storage of such a liquid product with added carbohydrates only, which teaches away from the present claims. It is neither disclosed nor suggested that long term storage at high temperatures of a liquid product containing said strain may be performed in case metabolized carbohydrates are omitted. As such, it is clear that *Reniero* merely discloses that "Lactic acid bacteria are utilized as fermenting agents for the preservation of food taking benefit of a low pH and the

action of fermentation products generated during the fermentative activity thereof to inhibit the growth of spoilage bacteria. To this end, lactic acid bacteria have been used for preparing a variety of different foodstuff such as cheese, yogurt and other fermented dairy products from milk." See, *Reniero*, page 1, lines 17-21.

Reniero, like *Fleming*, also does not disclose or suggest that the liquid product could comprise living microorganisms selected from the group consisting of *Bifidobacterium*, *Streptococcus*, *Lactococcus*, *Enterococcus* and mixtures of the same. *Reniero* discloses only *Lactobacillus* and does not discuss the possibility of the liquid product containing other genera of probiotics.

At no place in the disclosures do either *Fleming* or *Reniero* disclose or suggest a water- or milk-based liquid product comprising living microorganisms selected from the group consisting of *Bifidobacterium*, *Streptococcus*, *Lactococcus*, *Enterococcus* and mixtures of the same and has a pH from about 4 to about 7.5 in accordance with the present claims.

What the Patent Office has done is to rely on hindsight reconstruction of the claimed liquid product. Applicants respectfully submit that it is only with a hindsight reconstruction of Applicants' claimed liquid product that the Patent Office is able to even attempt to piece together the teachings of the prior art so that the claimed liquid product is allegedly rendered obvious. Instead, the claims must be viewed as a whole as defined by the claimed liquid product and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

In sum, *Fleming* and *Reniero*, alone or in combination fail to disclose or suggest each and every element of independent Claim 1. Moreover, *Fleming* and *Reniero* fail to teach, suggest or even recognize the advantages, benefits and/or properties of a water- or milk-based liquid product in accordance with the present claims. As a result, independent Claim 1, along with Claims 2–7 that depend therefrom, is novel and nonobvious over the cited references.

Accordingly, Applicants respectfully request that the rejection of the pending claims under 35 U.S.C. §103(a) in view of *Fleming* and *Reniero* be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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